IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:
Goldenberg *et al.*

Confirmation No.: 3453

Application No.: 09/590,284

Art Unit: 1644

Filed: June 9, 2000

Examiner: Ilia Ouspenski

For: **IMMUNOTHERAPY OF AUTOIMMUNE DISORDERS USING ANTIBODIES WHICH TARGET B-CELLS**

DECLARATION UNDER 37 C.F.R. §1.132

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

I, Don L. Siegel, Ph.D., M.D., being duly warned, hereby declare and say:

1. I am Associate Professor & Vice-Chair of the Department of Pathology & Laboratory Medicine at the University of Pennsylvania.

2. I have a Ph.D. degree from Harvard University and an M.D. degree from the University of Pennsylvania . I am the principal author of numerous articles related to human monoclonal autoantibodies and alloantibodies. My *curriculum vitae* is attached.

3. I am being compensated for preparing this declaration at my normal consulting rate.

4. I have reviewed the Official Action dated December 27, 2004 in the captioned application. I also have reviewed U.S. Patent No. 5,593,676 ("the Bhat patent") and Bhat *et al.* (1993), *Human antilipid A monoclonal antibodies bind to human B cells and the i antigen on cord red blood cells*, J. Immunol., Vol. 151(9): 5011-5021 ("Bhat *et al.*").

5. I am informed that there is a two-part test for determining whether a claim is obvious. This test requires considering whether the prior art (i) would have suggested to one of

ordinary skill in the art that the claimed invention should be carried out and (ii) would have had a reasonable likelihood of success, viewed in the light of the prior art.

6. The Examiner states that Bhat contemplates using anti-B cell antibodies to treat autoimmune diseases, such as multiple sclerosis. See Office Action at page 4. I disagree with the Examiner's characterization of the Bhat patent with respect to treatment of multiple sclerosis, for the reasons below. Also, it is my opinion that one of ordinary skill in the art would not have had a reasonable likelihood of success in using anti-B-cell antibodies for treating autoimmune disease based on the teachings of the Bhat patent.

7. The only reference to multiple sclerosis in the Bhat patent is at column 1, lines 33-40:

> These autoimmune diseases can be extremely destructive, as is evidenced by diabetes, rheumatoid arthritis, neuronal diseases, such as multiple sclerosis, and the like. While in many cases, the disease is associated with T-cell attack, in some of the diseases, there may be a B-cell component, and in other diseases, such as rheumatoid arthritis and lupus nephritis, the primary mediator may be B-cells.

This reference to multiple sclerosis clearly is in the context of a T-cell mediated disease and does not contain any suggestion that multiple sclerosis is a B-cell mediated disease. One of ordinary skill in the art would have read this paragraph in the context of the prevailing view in immunology that multiple sclerosis is a T-cell mediated autoimmune disease. Accordingly, it is my view that Bhat would not have suggested to one of ordinary skill in the art that multiple sclerosis might be a B-cell mediated disease.

8. Further review of the Bhat patent and Bhat *et al.* demonstrates that the data presented by Bhat would not have provided one of ordinary skill in the art with a reasonable expectation that autoimmune disease could be treated using an anti-B cell antibody.

9. First, it is clear that the 216 antibody described in the Bhat patent is not B-cell specific. See, for example, the description at column 6, lines 35-55 of the Bhat patent that shows that the 216 antibody binds to the *i* and *I* antigens present on red blood cells. One of ordinary skill in the art would not have been motivated to treat an autoimmune disease with a non-specific antibody that binds to red blood cells. Moreover, even if the person of ordinary skill tried to use

the 216 antibody for treating autoimmune disease there would not have been a reasonable expectation of success because of the lack of specificity of Bhat's 216 antibody.

10. The lack of binding specificity of the '216 antibody is further demonstrated in the Bhat article that describes that 216 is a polyreactive antibody. Thus, for example, the abstract of the Bhat article describes that 216 binds to "the lipid A domain of bacterial LPS" together with "the i Ag present on cord RBC, a ligand on human B lymphocytes and to certain autoantigens." Upon reading the Bhat article one of ordinary skill in the art would not have been motivated to use the 216 antibody for treating any B-cell mediated disease, let alone autoimmune disease, because of the antibody's polyreactivity. Moreover, this polyreactivity would not have led to any reasonable expectation of success in treating autoimmune disease.

11. The Bhat patent also states that the 216 antibody was isolated by incubating lymphocytes from a patient with nodular lymphoma with LPS and fusing the lymphocytes to a heteromyeloma cell line. See column 4 at lines 35-38. Accordingly, it appears that the lymphoma patient already produced the 216 antibody. Bhat *et al.* states that the patient had Hodgkin's lymphoma. See page 5102, left column, last full paragraph. Hodgkin's lymphoma is a B-cell lymphoma.

12. The fact that a patient suffering from a B-cell lymphoma produced the 216 antibody would provide further confirmation to one of ordinary skill in the art that the antibody would not be effective for treating B-cell mediated disease. Specifically, the fact that the patient suffered from a disease caused by B-cell proliferation while producing the 216 antibody demonstrates that the antibody is ineffective in suppressing B-cell proliferation *in vivo*.

13. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

3/28/05
Date

Don L. Siegel
Don L. Siegel, Ph.D., M.D.

UNIVERSITY OF PENNSYLVANIA -- SCHOOL OF MEDICINE
Curriculum Vitae

Date: April, 2005

Donald L. Siegel, Ph.D., M.D.

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Lansdale, PA 19446

Office Address: Division of Transfusion Medicine/6 Founders Pavilion
Department of Pathology & Laboratory Medicine
HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA
3400 Spruce Street
Philadelphia, PA 19104-4283

Education:

1973-77	Sc.B.	Brown University (Biophysics)
1977-83	Ph.D.	Harvard University (Biophysics)
1983-87	M.D.	University of Pennsylvania

Postgraduate Training and Fellowship Appointments:

1987-89	Resident in Clinical Pathology, HUP, Philadelphia, PA
1989-90	Chief Resident, Division of Laboratory Medicine, HUP, Philadelphia, PA
1990-91	Fellowship, Transfusion Medicine, HUP, Philadelphia, PA

Faculty Appointments:

1987-89	Assistant Instructor, Dept. of Pathology & Lab. Med., Univ. of PA School of Medicine, Philadelphia, PA
1989-91	Instructor, Dept. of Pathology & Lab. Med., Univ. of PA School of Medicine, Philadelphia, PA
1991-92	Lecturer, Dept. of Pathology & Lab. Med., Univ. of PA School of Medicine, Philadelphia, PA
1992-00	Assistant Professor of Pathology & Lab. Med., Univ. of PA School of Medicine, Philadelphia, PA
2000-	Associate Professor of Pathology & Lab. Med., Univ. of PA School of Medicine, Philadelphia, PA

Hospital and Administrative Appointments:

1990-96	Hospital Transfusion Committee, Member, HUP
1991-	Attending Physician, Blood Bank/Transfusion Medicine Section, Department of Pathology & Lab. Medicine, HUP
1992-96	Vice-Chairman, Hospital Transfusion Committee, HUP
1997-	Attending Physician, Department of Pathology & Lab Medicine, Presbyterian Hospital
2000-2003	Director, Blood Bank/Transfusion Medicine Section, Department of Pathology & Lab. Medicine, University of Pennsylvania Medical Center
2000-	Director, ACGME-accredited Fellowship Program in Blood Banking/Transfusion Medicine
2000-	Member for Oversight of Blood Usage, Clinical Effectiveness and Quality Improvement Committee
2002-	Director, Translational Research, Department of Pathology & Lab Medicine
2002-	Member, Executive Committee, Department of Pathology & Lab Medicine

2003-	Vice-Chair, Department of Pathology & Lab Medicine
2003	Chief, Division of Transfusion Medicine, Department of Pathology & Lab Medicine

Specialty Certification:

1992	The American Board of Pathology

Licensure: Pennsylvania

Awards, Honors, and Membership in Honorary Societies:

1977	elected to Sigma Xi
1977	Honors in Biophysics, Brown University, undergraduate thesis: "Application of non-equilibrium thermodynamics to plasma membrane transport"
1977-83	NIH Pre-Doctoral Fellowship in the laboratory of Dr. Daniel Branton, Harvard University, Ph.D. dissertation: "Purification and characterization of human erythrocyte band 4.9, an actin bundling protein"
1983	Young Investigator Award, First Prize Recipient, Boston Blood Club, Harvard Medical School
1983-85	Measey Foundation Scholar, University of Pennsylvania School of Medicine
1988	2 Young Investigator Awards, Academy of Clinical Laboratory Physicians and Scientists, 1988 Annual Meeting
1990	Berwick Resident Teaching Award, Department of Pathology & Laboratory Medicine, University of Pennsylvania
1991-92	Julius Erving Research Award of the Lupus Foundation of the Delaware Valley
1991-92	National Blood Foundation Research Award
1991-94	Clinical Investigator Award (K08), National Heart, Lung, and Blood Institute, NIH
1993-95	Basil O'Connor Scholar Research Award, March of Dimes Birth Defects Foundation
1996-97	National Blood Foundation Research Award
1996	National Blood Foundation Scholar
1998	Peter C. Nowell Teaching Award, Department of Pathology & Laboratory Medicine, University of Pennsylvania
2000	Leonard Berwick Memorial Teaching Award, University of Pennsylvania School of Medicine
2001	elected to John Morgan Society
2003	Philadelphia Antiques Show Proceeds Awardee, Board of Women's Visitors, University of Pennsylvania Medical Center
2003	Pennsylvania Biotechnology Greenhouse Award
2003	Christian R. and Mary F. Lindback Foundation Award for Distinguished Teaching, University of Pennsylvania

Memberships in Professional and Scientific Societies:

Regional Committees:

Member, Medical Advisory Committee, Penn-Jersey Division of the American Red Cross

National Societies:

American Association for Cell Biology

New York Academy of Science
American Association for the Advancement of Science
American Association of Blood Banks
American Society of Hematology
American Society for Apheresis
John Morgan Society

National Scientific Committees:

Member, Scientific Review Panel, Program Project on Prion Diseases, National Institute on Aging, 1998
Member, NIH/AABB-Sponsored Scientific Think Tank on "Setting the Research Agenda for Immunobiology in Transfusion Medicine", 1999
Member, Scientific Subcommittee on Hemoglobin/Red Cell, American Society of Hematology, 1999-03
Member, Clinical Applications and Standards Committee, American Society for Apheresis, 2004-

International Scientific Committees:

Coordinator, 4th International Workshop on Monoclonal Antibodies Against Human Red Blood Cells and Related Antigens, Paris, 1999-2001

Academic Committees at the University of Pennsylvania and Affiliated Hospitals:

1992-	Faculty Interviewer, Committee on Admissions, School of Medicine
1992-96	Medical Student Advisor, School of Medicine
1994-	Member, Faculty Advisory Committee, Transfusion Medicine Research Training Program (NIH T32 Award)
1997-	Member, Immunology Graduate Group
1997-	House Mentor, Combined Degree Mentoring Program, School of Medicine
2000	Member, Faculty Advisory Committee, Hemostasis/Thrombosis Research Training Program (NIH T32 Award)
2000	Chair, Committee for Transfusion Medicine Research Training Program (NIH T32 Award)

Major Teaching and Clinical Responsibilities for the University of Pennsylvania and Affiliated Hospitals:

1. Course Director for Frontiers of Medical Science 505 Course (Pathology 305), "Effective Use of Clinical Laboratory Tests", School of Medicine, course offered once per year
2. Course Director for Pathology elective, "Immunohematology" (Pathology 323), School of Medicine, offered each month
3. Daily attending rounds, Blood Bank/Transfusion Medicine Section, HUP; 3 months/year
4. Seminars on Transfusion Medicine to rotating fellows, residents, medical students, throughout year
5. Didactics on Transfusion Medicine to Hematology/Oncology Fellows, HUP, twice per year
6. Morning report attending, Laboratory Medicine Residents, HUP; 2 months/year
7. Immunology (ID101), lecturer (2 one-hour lectures on Immunohematology) and medical student section leader (5 hours/week x 4 weeks), School of Medicine *(course now replaced by Curriculum 2000)*

8. Pathology 200, lecturer (2 one-hour lectures on Transfusion Medicine) and medical student section leader for Heme/Onc Bridge (4 two-hour meetings), School of Medicine *(course now replaced by Curriculum 2000)*
9. Pathologic Processes and Clinical Responses (Curriculum 2000), lecturer (2 one-hour lectures on Transfusion Medicine); medical student section leader for Transfusion Medicine laboratory (one three-hour session), School of Medicine
10. Immunology 999, research seminar to Immunology Group graduate students, once/year
11. Supervision of post-doctoral fellows and students in laboratory

Other Teaching:

Co-Director of Cold Spring Harbor Laboratory Course, "Phage Display of Combinatorial Antibody Libraries," given yearly since 1996 in the Fall, Cold Spring Harbor, NY

Lecture, "Practical and technical issues regarding phage display technology," 4th International Workshop on Monoclonal Antibodies Against Human Red Blood Cells and Related Antigens, Paris, 2001

Lectures by Invitation:

February, 1981	*The Red Cell Cytoskeleton.* Workshop at ICN Meeting, Differentiation and Function of Hematopoietic Cell Surfaces, Keystone, CO.
June, 1981	*Cytoskeletal Structures.* Cold Spring Harbor Symposium, Organization of the Cytoplasm, Cold Spring Harbor, NY.
November, 1982	*Human Erythrocyte Band 4.9.* 22nd Annual Meeting, American Society for Cell Biology, Baltimore, MD.
December, 1982	*Human Erythrocyte Band 4.9.* Department of Hematology, St. Elizabeth's Hospital, Boston, MA.
January, 1983	*Human Erythrocyte Band 4.9.* Department of Cell and Developmental Biology, Harvard University, Boston, MA.
April, 1983	*Human Erythrocyte Band 4.9.* Boston Blood Club, Harvard Medical School, Boston, MA.
June, 1983	*Band 4.9, an Actin-Bundling Protein.* Department of Hematology/Oncology, Children's Hospital, Boston MA.
June, 1983	*Band 4.9, an Actin-Bundling Protein.* Department of Biochemistry and Molecular Biology, Harvard University, Boston, MA.
August, 1983	*Band 4.9, an Actin-Bundling Protein.* Red Cell Gordon Conference, Portsmouth, NH.
December, 1983	*Band 4.9, an Actin-Bundling Protein.* 23rd Annual Meeting, American Society for Cell Biology, San Antonio, TX.
January, 1984	*Human Erythrocyte Cytoskeletal Organization -- Normal and Pathologic States.* Hematology Department, Children's Hospital of Philadelphia, Philadelphia, PA.
February, 1984	*The Human Erythrocyte Cytoskeleton.* Cell Motility Club, Department of Anatomy, University of Pennsylvania, School of Medicine, Philadelphia, PA.

May, 1985 — *The Relationship Between the Structure and Function of the Human Erythrocyte Membrane.* Department of Pathology and Laboratory Medicine, University of Pennsylvania, School of Medicine, Philadelphia, PA.

November, 1987 — *Differential Expression of Activation Antigens on Peripheral Blood Lymphocytes in Renal Allograft Recipients During Episodes of Rejection and Infection.* 8th Annual Philadelphia Regional Immunology Conference, Philadelphia, PA.

June, 1988 — *Differential Expression of Activation Antigens on Peripheral Blood Lymphocytes in Renal Allograft Recipients During Episodes of Rejection and Infection.* 7th Annual Meeting, American Society of Transplant Physicians, Chicago, IL.

June, 1988 — *Distinguishing Rejection from Viral Infection in Renal Allograft Recipients Using Flow Cytometry.* Annual Meeting, Academy of Clinical Laboratory Physicians and Scientists, Cincinnati, OH.

June, 1988 — *Monitoring Patients with Pancreas Allografts.* Annual Meeting, Academy of Clinical Laboratory Physicians and Scientists, Cincinnati, Ohio.

February, 1991 — *Molecular Dissection of Human Red Cell Membrane Antigens.* Department of Pathology, SUNY Stony Brook School of Medicine, Stony Brook, New York.

April, 1991 — *Molecular Dissection of Human Red Cell Membrane Antigens.* Department of Pathology, University of Chicago, Chicago, Ill.

April, 1991 — *Molecular Dissection of Human Red Cell Membrane Antigens.* Department of Laboratory Medicine, Yale School of Medicine, New Haven, Conn.

May, 1991 — *Molecular Dissection of Human Red Cell Membrane Antigens.* Lindsley F. Kimball Research Institute of the New York Blood Center, New York, NY.

November, 1992 — *Production of Human Red Cell Antibodies in Bacteria by Repertoire Cloning.* Plenary Session, 45th Annual Meeting of the American Association of Blood Banks, San Francisco, CA.

April, 1993 — *In Vitro Production of Anti-Red Cell Antibodies.* Pennsylvania Society for Medical Technologists, Annual Meeting, Valley Forge, PA

October, 1993 — *Expression and Characterization of Recombinant Anti-Rh(D) Antibodies on Filamentous Phage: A Model System for Isolating Human Red Cell Antibodies by Repertoire Cloning.* The Center for Blood Research, Boston, MA.

October, 1993 — *Isolation of Recombinant Human Anti-Rh(D) Antibodies From Libraries Expressed on M13 Phage.* 46th Annual Meeting of the American Association of Blood Banks, Miami, FL.

November, 1993 — *Blood Component Therapy.* CME seminar, Doylestown Hospital, Doylestown, PA.

July, 1994 — *Isolation of Human Anti-Red Blood Cell Antibodies by Repertoire Cloning.* International Conference on Immunoglobulin Gene Expression in Development and Disease, The New York Academy of Sciences, Montreal, Quebec, Canada.

January, 1995 — *Production of Recombinant Anti-Red Blood Cell Antibodies on Filamentous Bacteriophage.* Visiting Professor, University of Tennessee, Memphis, Tennessee.

September, 1996 — *Molecular Characterization of the Human Anti-Rh Immune Response Using Fab-Phage Display*. Grand Rounds, Department of Pathology & Laboratory Medicine, University of Pennsylvania School of Medicine, Philadelphia, PA

October, 1996 — *A Plethora of Human Monoclonal Anti-Rh Antibodies Isolated Using Phage Display and Magnetically-Activated Cell Sorting,* Plenary Session, 49th Annual Meeting of the American Association of Blood Banks, Orlando, FL.

October, 1996 — *Molecular Characterization of the Human Anti-Rh Immune Response Using Fab-Phage Display*. Ortho Diagnostics Systems, Inc., Raritan, NJ.

November, 1996 — *Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display and Magnetically-Activated Cell Sorting*. Wistar Institute, Philadelphia, PA.

November, 1996 — *Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display and Magnetically-Activated Cell Sorting*. 1996 Cold Spring Harbor Laboratory Course on Monoclonal Antibodies from Combinatorial Libraries, Cold Spring Harbor, NY.

November, 1996 — *Molecular Characterization of the Human Anti-Rh Immune Response Using Fab-Phage Display*. Lindsley F. Kimball Research Institute of the New York Blood Center, New York, NY.

December, 1996 — *Highly-Efficient Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display and Magnetically-Activated Cell Sorting*. Seventh IBC Conference on Antibody Engineering, San Diego, CA.

December, 1996 — *Efficient Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display: Applications in Transfusion Medicine*. Immunology Group, Smith Kline Beecham, Inc., King of Prussia, PA.

January, 1997 — *Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display: Applications in Transfusion Medicine*. Scripps' Research Institute, La Jolla, CA.

January, 1997 — *Molecular Characterization of the Human anti-Rh Immune Response Using Fab/Phage Display*. Immunology Colloquium, Immunology Graduate Group, University of Pennsylvania.

May, 1997 — *Monoclonal Bacteriophage Antibodies*. 1997 Illinois Association of Blood Banks Quad State blood bank meeting, Chicago, IL.

May, 1997 — *Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display: Applications in Immunohematology*. Department of Immunology and Microbiology, Allegheny University of the Health Sciences, Philadelphia, PA.

September, 1997 — *Recombinant Phage-Displayed Human Anti-Red Blood Cell Antibodies and Blood Banking: A New Way to Type Blood.* Delaware Valley Blood Bank Club, Penn-Jersey Red Cross, Philadelphia, PA.

September, 1997 — *Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display: Applications in Transfusion Medicine*. Pathology Department Grand Rounds, New York Hospital/Cornell Medical Center, New York, NY.

October, 1997 — *New Approaches to Monoclonal Antibody Production.* Annual Seminar, 50th Annual Meeting of the American Association of Blood Banks, Denver, CO.

November, 1997 — *Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display and Magnetically-Activated Cell Sorting.* 1997 Cold Spring Harbor Laboratory Course on Phage Display of Combinatorial Antibody Libraries, Cold Spring Harbor, NY

December, 1997 — *Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display: Applications in Immunohematology.* Prolifaron, Inc., La Jolla, CA.

December, 1997 — *Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display: Applications in Immunohematology.* Gamma Biologicals, Inc., Houston, TX.

February, 1998 — *A New Approach for Human Monoclonal Antibody Production in Transfusion Medicine: Bacteriophage-Displayed Antibodies as Reagents for Blood Typing and Dissecting Rh Antigen Epitope Topology.* Department of Pathology, UCLA School of Medicine, Los Angeles, CA.

April, 1998 — *Bacteriophage-Displayed Antibodies as Novel Reagents for Blood Typing and Understanding the Development of Human Immune Responses.* Laboratory Medicine Divisional Conference, Department of Pathology & Laboratory Medicine, University of Pennsylvania School of Medicine, Philadelphia, PA.

April, 1998 — *Molecular Characterization of the Human Anti-Rh Immune Response Using Fab/Phage Display.* Immunology Seminar Series, Mt. Sinai School of Medicine, New York, NY.

April, 1998 — *New Insights into the Immunobiology of the Rh Antigen as Revealed by Phage Display Technology.* NHLBI, NIH, Bethesda, MD.

May, 1998 — *A New Approach for Human Monoclonal Antibody Production: Bacteriophage-Displayed Antibodies as Reagents for Blood Typing and Dissecting Rh Antigen Epitope Topology.* 1998 Reference Laboratory Conference, American Red Cross, Washington, D.C.

June, 1998 — *Molecular Characterization of the Human Anti-Rh Immune Response Using Fab/Phage Display.* Dyax Corporation, Cambridge, MA.

June, 1998 — *The Dwindling Supply of Human Antisera for Blood Group Typing: A Solution Using Phage Display Technology.* Annual Meeting of the Academy of Clinical Laboratory Physicians and Scientists, Boston, MA.

August, 1998 — *Molecular Characterization of the Human Red Cell anti-Rh Immune Response Using Fab/phage Display.* Abgenix, Inc., Freemont, CA.

October, 1998 — *New Insights into the Immunobiology of the Human Rh Antigen as Revealed by Phage Display Technology.* Department of Pathology, Beth Israel Hospital, Harvard Medical School, Boston, MA.

November, 1998 — *Epitope Migration of Anti-D Antibodies.* 51st Annual Meeting of the American Association of Blood Banks, Philadelphia, PA.

November, 1998 — *Isolation of Human IgG Platelet Autoantibodies Using Phage Display.* Plenary Session, 51st Annual Meeting of the American Association of Blood Banks, Philadelphia, PA.

November, 1998 — *Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display and Magnetically-Activated Cell Sorting.* 1998 Cold Spring Harbor Laboratory Course on Phage Display of Combinatorial Antibody Libraries, Cold Spring Harbor, NY.

December, 1998 — *Epitope Migration: Anti-Rh(D) Antibodies as a Model for Human Immunogenicity.* 40th Annual Meeting of the American Society for Hematology, Miami, FL.

January, 1999 — *New Insights Into Human Monoclonal Anti-Rh and Anti-Platelet Antibodies as Revealed by Phage Display.* Hematology-Oncology Section Research Conference, Department of Medicine, University of Pennsylvania Medical Center.

January, 1999 — *Characterization of Human Monoclonal Anti-RBC and Anti-Platelet Antibodies Using Phage Display.* Hematology Grand Rounds, Mt. Sinai School of Medicine, New York, NY.

February, 1999 — *New Insights Into Human Monoclonal Anti-Rh and Anti-Platelet Antibodies as Revealed by Phage Display.* Laboratory Medicine Divisional Conference, Department of Pathology & Laboratory Medicine, University of Pennsylvania School of Medicine, Philadelphia, PA.

March, 1999 — *Use of Phage Display Technology for the Development of Blood Group Typing Reagents.* Cambridge Healthtech Institute's Phage Display -- Novel Therapeutics and Diagnostics: Applications in Product Development, Cambridge, MA.

April, 1999 — *Dissecting Human Auto- and Alloimmune Responses to RBCs and Platelets Using Phage Display Technology.* Lindsley F. Kimball Research Institute of the New York Blood Center, New York, NY.

May, 1999 — *Phage Display Technology and its Applications in the Field of Immunohematology and ITP.* 1999 International Society of Blood Transfusion, Jerusalem, Israel.

June, 1999 — *Recombinant Approaches for Developing Diagnostic Reagents in Transfusion Medicine.* Annual Meeting of the Academy of Clinical Laboratory Physicians and Scientists, Birmingham, AL.

September, 1999 — *Use of Repertoire Cloning and Antibody Engineering in the Design of Therapeutics* NIH/AABB-Sponsored Scientific Think Tank on "Setting the Research Agenda for Immunobiology in Transfusion Medicine," Bethesda, MD.

October, 1999 — *Application of Molecular Biology to Immunoglobulin Engineering.* Molecular Biology in Blood Transfusion, 24th International Symposium, The Netherlands.

November, 1999 — *Dissecting Human Auto- and Alloimmune Responses to RBCs and Platelets Using Phage Display Technology.* The Second Leonard Jarett MD Honorary Research Symposium, University of Pennsylvania School of Medicine.

November, 1999 — *Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display and Magnetically-Activated Cell Sorting.* 1999 Cold Spring Harbor Laboratory Course on Phage Display of Combinatorial Antibody Libraries, Cold Spring Harbor, NY.

November, 1999 — *Production of Large Repertories of Macaque mAbs to Human RBCs Using Phage Display.* 52nd Annual Meeting of the American Association of Blood Banks, San Francisco, CA.

November, 1999 — *Understanding Immunogenicity on a Molecular Level: New Insights Revealed by the Rh(D) Immune Response.* 52nd Annual Meeting of the American Association of Blood Banks, San Francisco, CA.

November, 1999 — *Mechanism of Rh immune globulin prophylaxis revisited.* 52nd Annual Meeting of the American Association of Blood Banks, San Francisco, CA.

May, 2000 — *Appropriate Use of Blood Products.* CME seminar, Phoenixville Hospital, Phoenixville, PA.

June, 2000 — *Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display.* NCI-sponsored workshop, Molecular Diversity-Based Discovery of Tumor-Specific Diagnostic Markers and Probes, Bethesda, MD.

September, 2000 — *Phage Display and anti-Rh(D) Repertoire.* Sixth Symposium on Platelet, Granulocyte and Red Cell Immunobiology, Amsterdam, Netherlands.

October, 2000 — *Epitope Migration of Anti-Rh(D) Antibodies and the Concept of Red Cell Antigen Immunogenicity.* Blood Research Institute, Milwaukee, Wisconsin.

November, 2000 — *What's a Clinically Significant Antibody?* 53rd Annual Meeting of the American Association of Blood Banks, Washington, D.C.

November, 2000 — *Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display and Magnetically-Activated Cell Sorting.* 2000 Cold Spring Harbor Laboratory Course on Phage Display of Combinatorial Antibody Libraries, Cold Spring Harbor, NY.

May, 2001 — *Staph Protein A Columns.* 22nd Annual Meeting of the American Society for Apheresis, Niagara Falls, NY.

July, 2001 — *Recombinant Monoclonal Antibody Technology.* 4th International Workshop on Monoclonal Antibodies Against Human Red Blood Cells and Related Antigens, Paris, France. *(Plenary Lecture)*

July, 2001 — *Structural Analysis of Monoclonal Antibodies to Blood Group Antigens.* Coordinator's Report, 4th International Workshop on Monoclonal Antibodies Against Human Red Blood Cells and Related Antigens, Paris, France.

October, 2001 — *Dissecting Human Auto- and Alloimmune Responses to RBCs and Platelets Using Phage Display Technology.* Microbiology and Immunology Seminar Series, MCP Hahnemann Univ. School of Medicine, Philadelphia, PA.

October, 2001 — *What's a Clinically Significant Antibody?* 54th Annual Meeting of the American Association of Blood Banks, San Antonio, TX.

October, 2001 — *Antibody Phage Display: Implications for Reagent Production and Treatment of Antibody-Mediated Disease.* Workshop on Application of Molecular Biology to Immunohematology, 54th Annual Meeting of the American Association of Blood Banks, San Antonio, TX.

November, 2001 — *Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display and Magnetically-Activated Cell Sorting.* 2001 Cold Spring Harbor Laboratory Course on Phage Display of Combinatorial Antibody Libraries, Cold Spring Harbor, NY.

December, 2001 — *Understanding Immunogenicity on a Molecular Level: New Insights Revealed by the Rh Immune Response.* Scientific Committee on Transfusion Medicine: The

Immune Response to Transfusion, 43rd Annual Meeting of the American Society for Hematology, Orlando, FL.

April, 2002 — *Thrombotic Thrombocytopenic Purpura (TTP): Exciting recent findings which have advanced our understanding of disease pathogenesis and treatment by plasmapheresis.* Pennsylvania Society for Clinical Laboratory Science Annual Meeting, King of Prussia, PA.

April, 2002 — *Dissecting Human Auto- and Alloimmune Responses to RBCs and Platelets Using Phage Display Technology: Diagnostic and Therapeutic Implications.* Department of Biologics Research, Merck Research Laboratories, Rahway, NJ.

May, 2002 — *Dissecting Human Auto- and Alloimmune Responses to RBCs and Platelets Using Phage Display Technology.* Transfusion Medicine Grand Rounds, Joint Harvard Program in Transfusion Medicine, Harvard Medical School, Boston, MA.

May, 2002 — *Isolation of Cell Surface-Specific Human Monoclonal Antibodies to Red Cells and Platelets Using Phage Display and Magnetically-Activated Cell Sorting.* New England Biolabs, Beverly, MA.

September, 2002 — *Developing New Diagnostic and Therapeutic Tools for Immune-Mediated Diseases Using Antibody Engineering.* Duhring Lecture, Division of Dermatology, University of Pennsylvania School of Medicine, Philadelphia, PA.

September, 2002 — *The Use of Phage Display to Develop Rational Therapies for the Treatment of Autoimmune Platelet Disorders (ITP).* Conference on Display Technologies Accelerating Drug Discovery, Strategic Research Institute, Long Branch, NJ.

October, 2002 — *Genetic Analyses of Human Immune Responses to Red Cells and Platelets.* Rheumatology Division Grand Rounds, UCSD, San Diego, CA.

October, 2002 — *Autoimmune Thrombocytopenic Purpura (ITP): Current Treatment Options and Those on the Horizon.* Department of Medicine Grand Rounds, UCSD, San Diego, CA.

October, 2002 — *Antibody Phage Display: Implications for Reagent Production and Treatment of Antibody-Mediated Disease.* Workshop on Application of Molecular Biology to Immunohematology, 55th Annual Meeting of the American Association of Blood Banks, Orlando, FL.

November, 2002 — *Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display and Magnetically-Activated Cell Sorting.* 2002 Cold Spring Harbor Laboratory Course on Phage Display of Combinatorial Antibody Libraries, Cold Spring Harbor, NY.

December, 2002 — *Cloning of Anti-Platelet Autoantibodies.* ITP Workshop, 44th Annual Meeting of the American Society for Hematology, Philadelphia, PA.

March, 2003 — *Phage Display Technology.* BioRexis, Inc., King of Prussia, PA.

May, 2003 — *Creating Diagnostic and Therapeutic Molecules Using Phage Display.* Hematology/Oncology Research Seminar Series, Children's Hospital of Philadelphia, Philadelphia, PA.

June, 2003 — *Antibody Phage Display for Reagent and Therapeutic Antibody Production.* Current Topics in Blood Banking Conference, University of Michigan, Ann Arbor, MI.

June, 2003 — *Etiology and Management of ITP.* Current Topics in Blood Banking Conference, University of Michigan, Ann Arbor, MI.

June, 2003 — *Antibody Phage Display for Reagent and Therapeutic Antibody Production.* Targeted Molecules, Inc., San Diego, CA

September, 2003 — *Blood Transfusion Risks.* Department of Urology Grand Rounds, University of Pennsylvania Medical Center, Philadelphia, PA.

September, 2003 — *Developing New Diagnostic and Therapeutic Tools for Immune-Mediated Diseases Using Antibody Engineering.* Renal Research Conference, University of Pennsylvania School of Medicine, Philadelphia, PA.

October, 2003 — *Phage Display Technology for the Development of Novel Diagnostic and Therapeutic Agents.* 12th Annual Meeting of the Great Lakes International Imaging and Flow Cytometry Association, Milwaukee, WI.

November, 2003 — *Diagnostic and Therapeutic Applications of Phage Display Technology.* Session on Emerging Technologies and Therapies in Transfusion Medicine, 56th Annual Meeting of the American Association of Blood Banks, San Diego, CA.

November, 2003 — *Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display and Magnetically-Activated Cell Sorting.* 2003 Cold Spring Harbor Laboratory Course on Phage Display of Combinatorial Antibody Libraries, Cold Spring Harbor, NY.

December, 2003 — *Characterization of an ITP Patient-Derived Anti-$\alpha_{2b}\beta_3$ Monoclonal Antibody that Inhibits Platelet Aggregation.* 45th Annual Meeting of the American Society for Hematology, San Diego, CA.

April, 2004 — *Transfusion Medicine Overview.* Weekly Conference, Division of Vascular Surgery, Department of Surgery, University of Pennsylvania Medical Center.

May, 2004 — *Therapeutic Apheresis/Extra-Corporeal Selective Extraction Techniques.* World Apheresis Association/American Association of Apheresis Joint Meeting, Miami, FL.

October, 2004 — *Phage Display Tools for Automated Blood Typing.* Plenary Session, 57th Annual Meeting of the American Association of Blood Banks, Baltimore, MD.

October, 2004 — *Diagnostic and Therapeutic Applications of Phage Display Technology.* Session on Emerging Technologies and Therapies in Transfusion Medicine, 57th Annual Meeting of the American Association of Blood Banks, Baltimore, MD.

November, 2004 — *Isolation of Cell Surface-Specific Human Monoclonal Antibodies Using Phage Display and Magnetically-Activated Cell Sorting.* 2004 Cold Spring Harbor Laboratory Course on Phage Display of Peptides and Proteins, Cold Spring Harbor, NY.

December, 2004 — *Review of Different Kinds of Blood Components and the Indications and Risks of Their Use.* Grand Rounds CME Program, The Chester County Hospital, West Chester, PA.

January, 2005 — *ITP and the Mechanism of Action of Staphylococcal Protein A Plasmapheresis.* Allergy & Immunology Divisional Conference, University of Pennsylvania School of Medicine, Philadelphia, PA.

May, 2005	*Diagnostic and Therapeutic Applications of Phage Display Technology.* The 8th Leonard Jarett MD Honorary Research Symposium, University of Pennsylvania School of Medicine. *(scheduled)*
June, 2005	*Transfusion Medicine Overview.* Weekly Teaching Conference, Division of Maternal-Fetal Medicine, HUP. *(scheduled)*
June, 2005	*Use of Phage Display to Study Human Autoimmune Disease: ITP as a Paradigm.* "Pemphigus 2005, Progress and Future Directions", an international meeting sponsored jointly by the International Pemphigus Foundation, The American Autoimmune Related Diseases Association, and the NIH NIAMS, Bethesda. MD. *(scheduled)*
July, 2005	*Graduate Pathology Education: What are we missing for a competent trainee product for the future?* Annual Summer Meeting, Association of Pathology Chairs, Mont-Tremblant Quebec, Canada. *(scheduled)*
October, 2005	*Overview of Antibody and Peptide Phage Display.* Program on Applications of Phage Display to Blood Transfusion Medicine, 58th Annual Meeting of the American Association of Blood Banks, Seattle, WA. *(scheduled)*

Organizing Roles in Scientific Meetings:

Nov 1999-July 2001	Coordinator, 4th International Workshop on Monoclonal Antibodies Against Human Red Blood Cells and Related Antigens, Paris (meeting July 20-21, 2001).
Oct 2004-May 2006	Scientific Program Co-coordinator, 27th Annual Meeting of the American Society for Apheresis, Las Vegas, NV (meeting May 25-27, 2006).
Feb 2005-Oct 2005	Program Coordinator, "Applications of Phage Display to Blood Transfusion Medicine", Annual Meeting of the American Association of Blood Banks, Seattle, WA (meeting October 15-18, 2005).

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Research Publications, peer reviewed:

Palatt P.J., Prusch R.D., **Siegel D.L.**: The diffusional and osmotic water permeability of the hindgut cuticle of larval Sarcophaga bullata, *J Insect Physiology* 23:1113-1116, 1977.

Siegel D.L., Goodman S.R., Branton D.: The effect of endogenous proteases on the spectrin binding proteins of human erythrocytes, *Biochimica Biophysica Acta* 598:517-527, 1980.

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Siegel D.L., Branton D.: Partial purification and characterization of an actin-bundling protein, band 4.9, from human erythrocytes, *J Cell Biology* 100:775-785, 1985.

Siegel D.L., Fox I., Asplund M., Dafoe D., Power M., Zellers L., Barker C.F., Prystowsky M.: Distinguishing rejection from CMV infection in renal transplant recipients using flow cytometry, *Clinical Immunol Immunopath* 51:157-171, 1989.

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Czerwinski M, **Siegel D.L.**, Moore J.S., Spitalnik P.F., Spitalnik S.L.: Construction of bacteriophage expressing mouse monoclonal Fab fragments against the human MN glycophorin blood group antigens, *Transfusion* 35:137-144, 1995.

Siegel D.L.: Isolation of human anti-red blood cell antibodies by repertoire cloning, *Annals of the New York Academy of Sciences* 764:547-558, 1995.

Wojczyk B.S., Czerwinski M., Stwora-Wojczyk M.M., **Siegel D.L.**, Abrams W.R., Wunner W.H., Spitalnik S.L.: Purification of a secreted form of recombinant rabies virus glycoprotein: Comparison of two affinity tags, *Protein Expression and Purification* 7:183-193, 1996.

Pereira S., Van Belle P., Elder D., Maruyama H., Jacob L., Sivanandham M., Wallack M., **Siegel D.L.**, and Herlyn D.: Combinatorial antibodies against human malignant melanoma, *Hybridoma* 16:11-16, 1997.

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Siegel D.L., Chang, T.Y., Russell, S., Bunya, V.Y.: Isolation of cell surface-specific human monoclonal antibodies using phage display and magnetically-activated cell sorting: Applications in immunohematology, *J Immunological Methods* 206:73-85, 1997.

Wang L., Radic M.Z., **Siegel D.L.**, Chang T., Bracy J., Galili U.: Cloning of anti-Gal Fabs from combinatorial phage display libraries: Comparison of Fab expression in pComb3H and pComb8 phage, *Molecular Immunology* 34:609-618, 1997.

Siegel D.L.: The human immune response to red blood cell antigens as revealed by repertoire cloning, *Immunologic Research* 17:239-251, 1998.

Chang T.Y., **Siegel D.L.**: Genetic and immunological properties of phage-displayed human anti-Rh(D) antibodies: Implications for Rh(D) epitope topology, *Blood* 91:3066-3078, 1998.

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Arepally G.M., Kamei S., Park K.S., Kamei K., Li Z.Q., Liu W., **Siegel D.L.**, Kisiel W., Cines D.B., Poncz M.: Preparation and characterization of a murine monoclonal antibody that mimics heparin-induced thrombocytopenia (HIT) antibodies, *Blood* 93: 110-118, 2000. (Plenary Paper)

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Roark J.H., Bussel J.B., Cines D.B., **Siegel D.L.**: Genetic analysis of autoantibodies in ITP reveals evidence of clonal expansion and somatic mutation, *Blood* 100:1388-1398, 2002.

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Silverman G.J., Goodyear C.S., and **Siegel D.L.**: On the mechanism of Staphylococcal protein A immunomodulation, *Transfusion* 45:274-280, 2005.

Payne A.S., Ishii K., Kacir S., Lin C., Li H., Hanakawa Y., Tsunoda K., Amagai M., Stanley J.R., **Siegel D.L.**: Genetic and functional characterization of human pemphigus vulgaris monoclonal autoantibodies isolated by phage display, *J. Clinical Invest* 115:888-899, 2005.

Kucher C., Steere J., Elenitas R., **Siegel D.L.**, Xu X.: Nephrogenic systemic fibrosis with diaphragmatic involvement in a patient with respiratory failure, *J Amer Acad Derm, in press.*

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Herlyn D., Pereira S., Maruyama H., Van Belle P. Elder D., Jacob L., Somasundaram R., Wallack M., and **Siegel D.L.**: Identification of tumor antigens using antibody phage display. In Thibeault, C. (Ed.) Antibody Engineering: New Technologies, Applications, & Commercialization, Biomedical Library Series, IBC, Boston, 1996.

Siegel D.L. and Chang T: Isolation of cell surface-specific human monoclonal antibodies using phage display and magnetically-activated cell sorting. In Hori, W. (Ed.) Antibody Engineering II, Biomedical Library Series, IBC, Boston, 1997, 263-272.

Siegel D.L. Understanding immunogenicity on a molecular level: New insights revealed by the Rh(D) immune response. In The Compendium 1999, American Association of Blood Banks, Bethesda, 1999, 393-396.

Abstracts:

Siegel D.L., Branton D.: Human erythrocyte band 4.9. *J Cell Biology*, 95:265a, 1982.

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Siegel D.L., Fox I., Asplund M., Dafoe D., Power M., Prystowsky M.: Differential expression of activation antigens on peripheral blood lymphocytes in renal allograft recipients during episodes of rejection and infection. Eighth Annual Philadelphia Regional Immunology Conference, Philadelphia, PA, 1987.

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Wang L., Radic R.Z., **Siegel D.L.**, Galili U.: Characteristics of human anti-Gal genes. (presented at the Keystone Symposia on Molecular and Cellular Biology "Exploring and Exploiting Antibody and Ig Superfamily Combining Sites", Taos, March, 1996)

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Aqui N.A., Milone M.C., Sachs R., Stadtmauer E.A., Luger S., Shuster S., Porter D.L., Tsai D.E., Nasta S., Sachais B., O'Doherty U., **Siegel D.**, Sesok-Pizzini DA.: Peripheral CD34 counts are predictive of outcome in leukapheresis in Hodgkin's disease and non-Hodgkin's lymphoma patients, *Transfusion* 43:43A, 2003.

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Siegel D.L., Loftus J.C., and McMillan R.: Characterization of an ITP patient-derived anti-$\alpha_{2b}\beta_3$ monoclonal antibody that inhibits platelet aggregation, *Blood* 102:87a, 2003.

Siegel D.L.: Phage display tools for automated blood typing, *Transfusion* 44:2a, 2004. (Plenary Session abstract)

Kasner M., Luger S., Stadtmauer E., Schuster S., Tsai D., Nasta S., Oerl A., Lore A., Goldstein S., Mangan P., Sachs R., **Siegel D.L.**, Porter D.: Utility of prophylactic autologous stem cell collection for patients with acute myeloid leukemia in first remission, *Blood* 104:1872a, 2004.

Ishii K., Payne A., Kacir S., Hanakawa Y., Li H., Lin C., **Siegel D.L.**, Stanley J.R. Pemphigus vulgaris human monoclonal antibodies cause dissociation of human keratinocytes. 66th Annual Meeting of the Society for Investigative Dermatology, St. Louis, MO, May 2005.

Payne A.S., Ishii K., Kacir S., Lin C., Li H., Hanakawa Y., Tsunoda K., Amagai M., **Siegel D.L.**, Stanley J.R.. Isolation and characterization of human monoclonal antibodies from a pemphigus vulgaris patient by phage display. 66th Annual Meeting of the Society for Investigative Dermatology, St. Louis, MO, May 2005.

Editorials, Reviews, Chapters, Committee Reports:

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Siegel D.L.: Amphipathic Microcarriers. United States Patent Office #4,415,668, issued 11/15/83.

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Siegel D.L.: Panning Phage Display Libraries. Australian Patent Office #722978, issued 11/30/00.

Siegel D.L. Compositions, Methods, and Kits Relating to Anti-Platelet Autoantibodies and Inhibitors Thereof (pending).

Siegel D.L. Compositions, Methods, and Kits for Detection of an Antigen on a Cell and in a Biological Mixture (pending).